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Subject: Environmental Defense comments on Fluoroethylene (CAS# 75-02-5)

(Submitted via Internet 6/5/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and Edwin.L.Mongan-1@usa.dupont.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Fluoroethylene (CAS# 75-02-5).

Fluoroethylene, also called vinyl fluoride (VF), was sponsored by E.I. duPont de Nemours and Company. The submission is informative and complete, and the information provided in the robust summaries on studies addressing SIDS endpoints contains sufficient detail to permit a careful evaluation of the adequacy of individual studies.

VF is apparently used in the synthesis of polyvinyl fluoride, and the sponsor states than it can be released to the environment through waste streams, although no data were provided on the magnitude of those releases. Also, no information was presented on the potential for human exposure, although the sponsor maintains that available data indicate that there is little exposure to workers.

The sponsor contends that, with the exception of the biodegradation endpoint, existing data are sufficient to meet HPV requirements. We agree. Surrogate data from vinyl chloride (VC) are used to address the aquatic toxicity and reproductive and developmental toxicity endpoints. While we agree that vinyl chloride is an acceptable surrogate, our conclusion is based on knowledge not presented in the test plan or robust summaries. To be acceptable, the submission itself needs to provide sufficient rationale for use of VC as a surrogate for these endpoints. Therefore, we recommend that the sponsor prepare a table summarizing the similarities between VF and VC, including comparisons on structure, metabolism, molecular interactions, cell proliferation and carcinogenic activity.

We also note that VC is classified as a known human carcinogen, so the sponsor and EPA must also consider VF as a known human carcinogen if VC is used as a surrogate for VF.

Other comments are as follows:

1. The ECOSAR models used to estimate aquatic toxicity endpoints for VC do not appear to work well, so we recommend caution in interpreting those data. For example, ECOSAR grossly over predicts the toxicity to fish and algae but grossly under predicts toxicity to aquatic invertebrates. However, it is reasonable to assume that aquatic toxicity endpoints will be similar for VF and VC, so use of measured data for VC as a surrogate is acceptable.

2. The biodegradation models generated conflicting data for this endpoint,

so we agree with the sponsor's proposal to conduct a biodegradation study on VF.

3. VF is a multisite and multispecies carcinogen in rodents, with increased cancers evident at all doses tested; the lowest dose used was 25 ppm. The test plan states that the duPont AEL for VF is 1 ppm as an 8-hr TWA, although it is maintained that this level is never observed in the workplace. Based on the cancer dose response data in rodents and the knowledge that VF is positive in genetic toxicity tests, we urge the sponsor to significantly lower the current AEL.

4. A combined reproductive/developmental toxicity study on VC indicated that this substance is not a potent teratogen or reproductive toxin. We agree that these data can be used to fulfill requirements for VF for these endpoints.

Thank you for this opportunity to comment.

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